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No. 96-188

IN THE  
**Supreme Court of the United States**  
OCTOBER TERM, 1996

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GENERAL ELECTRIC COMPANY,  
WESTINGHOUSE ELECTRIC CORPORATION,  
and MONSANTO COMPANY,  
v. *Petitioners,*

ROBERT K. JOINER and KAREN P. JOINER,  
*Respondents.*

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On Writ of Certiorari to the  
United States Court of Appeals  
for the Eleventh Circuit

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**BRIEF OF  
CHEMICAL MANUFACTURERS ASSOCIATION  
AS AMICUS CURIAE  
IN SUPPORT OF PETITIONERS**

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---

*Amicus curiae* respectfully prays that this Court reverse the Eleventh Circuit's ruling in this case and reinstate the District Court's judgment in favor of the Petitioners. *Amicus* has obtained consent from all parties to file this brief. Correspondence evidencing consent has been provided to the Clerk of this Court.

### INTEREST OF AMICUS CURIAE \*

The Chemical Manufacturers Association ("CMA") is a non-profit trade organization whose member companies produce, market, and use industrial chemicals. Its members comprise more than 90 percent of the productive capacity for basic industrial chemicals in the United States. The chemical industry employs over a million workers in this country, and produces about 1.8 percent of the U.S. gross domestic product. On a value-added basis, the industry is about 10.3 percent of U.S. manufacturing. Petitioner Monsanto Company is a CMA member, as is General Electric Plastics, a business wholly-owned by Petitioner General Electric Company.

CMA is concerned about this case because the Eleventh Circuit's decision undermines this Court's ruling in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). *Daubert* requires that federal trial judges act as gatekeepers to determine "whether the reasoning or methodology underlying [an expert's] testimony is scientifically valid and . . . whether that reasoning or methodology properly can be applied to the facts in issue." *Id.* at 592-93. The Eleventh Circuit, however, has announced that when expert testimony is excluded under *Daubert*, the ruling is subject to "particularly stringent" review. On the other hand, if a court *admits* such testimony its ruling would be subject to no special scrutiny.

This outcome-dependent one-way strict scrutiny standard of review discourages trial courts from exercising the control over experts that *Daubert* requires, and it thrusts on appellate courts the kind of detailed factfinding for which trial courts are much better suited. Indeed, in this case the Eleventh Circuit did not address the experts'

\* No counsel for any party authored any part of this brief, and no person other than *amicus curiae*, its members, or its counsel made any monetary contribution to the preparation or submission of the brief.

reasoning and methodology, but focused instead on their qualifications and the sources of information on which they relied.

The inquiry into scientific validity that *Daubert* requires has led to better informed rulings on the admissibility of expert evidence, and ultimately to better informed verdicts, but the Eleventh Circuit's decision (and a similar decision from the Third Circuit) threaten its continued effectiveness. For CMA and its constituent members, who face putatively scientific testimony from a wide variety of experts, discouraging judicial gatekeeping in this area raises grave concerns. When experts are allowed to give opinions in court that are not the result of scientifically valid reasoning and methodology, defendants sometimes pay for injuries or damages they did not cause or that may not even exist. The American consumer also pays; prices go up and some products are never developed or never brought to market. *Daubert* has reduced the use of invalid and unreliable expert testimony, and this case should not be allowed to vitiate its salutary effect.

### STATEMENT OF THE CASE

The Plaintiffs (here Respondents) in this case are a husband and wife who claimed the husband's lung cancer was caused by his alleged exposure to PCBs (polychlorinated biphenyls). They also claimed he was exposed to furans and dioxins. All of these exposures allegedly resulted from the husband's work with transformers at the municipal utility where he was employed as an electrician. The District Court found the Plaintiffs' expert testimony on causation inadmissible under Rule 702 of the Federal Rules of Evidence, as interpreted by this Court in *Daubert*, and granted the Defendants' motion for summary judgment. *Joiner v. General Electric Co.*, 864 F.Supp. 1310 (N.D. Ga. 1994).

In particular, the trial court found there was insufficient evidence of exposure to furans and dioxins, and that the

expert testimony did not establish a scientifically valid link between PCBs and lung cancer. The experts had relied on animal studies, and while the court did not hold that testimony based on such studies was invariably inadmissible, in this case the reasoning connecting the studies to the conclusion that PCBs cause lung cancer in humans was fatally flawed. There were only two studies; both had involved massive doses; and one of the Plaintiffs' own experts had conceded their preliminary nature. *Id.* at 1323. Overall, the "analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue of [causation was] too wide." *Id.* at 1326 (quoting *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1360 (6th Cir.), *cert. denied*, 113 S.Ct. 84 (1992) (involving similar issues in the context of litigation concerning the anti-nausea drug Bendectin)).

Notwithstanding the District Court's careful and detailed analysis of the experts' reasoning and methodology, the Eleventh Circuit reversed, holding in a 2-1 decision that a trial judge's exclusion—*but not admission*—of expert testimony warrants "particularly stringent" review. *Joiner v. General Electric Co.*, 78 F.3d 524, 529 (11th Cir. 1996). The two judge majority then undertook its own reinterpretation of the Plaintiffs' evidence. The majority described the studies relied upon by the experts, but never discussed how the expert opinions were derived from those studies. This omission prompted the dissenting judge to observe that experts cannot simply cite studies "and then, with blue smoke and sleight of hand, leap to [conclusions.]" *Id.* at 537 (Smith, J., dissenting).

#### SUMMARY OF ARGUMENT

Because of its explicitly acknowledged bias against exclusion of questionable expert testimony, the Eleventh Circuit's one-way strict scrutiny standard of review is at odds with this Court's mandate in *Daubert* that district judges must act as gatekeepers to ensure the reliability and rele-

vance of expert scientific evidence. The one-way strict scrutiny approach, which has been adopted by only the Third and Eleventh Circuits, discourages trial judges from fulfilling this mandate. It also is contrary to the deference traditionally accorded trial court rulings about the admissibility of expert testimony. This deferential approach, which reflects recognition that such decisions require detailed case-by-case analysis, has not been altered by the adoption of the Federal Rules of Evidence. Although the rules have eliminated arcane procedural barriers to admissibility, they have not changed the requirement that expert testimony be reliable and trustworthy.

The Third Circuit, which the Appellate Court in this case cited in support of one-way strict scrutiny, *Joiner*, 78 F.3d at 529, has made clear that part of the rationale for such an approach is concern that if "district judges set the [admissibility] threshold too high . . . [it] will in fact force plaintiffs to prove their case twice." *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 750 (3d Cir. 1994), *cert. denied*, 115 S. Ct. 1253 (1995). The standard for reviewing the correctness of a trial court's ruling on the admissibility of expert testimony should not, however, depend on which party is most affected by the inquiry into reliability and relevance. Nor should it depend on how such a ruling might affect the ultimate outcome of a case. No matter which party is impacted, expert testimony should be excluded when an expert uses scientifically invalid reasoning and methodology.

The hazards of excessive review by an appellate court are nowhere more apparent than in this case. *Daubert* requires an assessment of an expert's reasoning and methodology, but unlike the trial court, the Eleventh Circuit looked only at the qualifications of the two experts whose testimony was at issue, and at the information upon which they had relied. The analytical gap between that information and the experts' conclusions was unaddressed, largely because the panel majority misunderstood and misapplied

this Court's admonition in *Daubert* to focus on principles and methodology rather than conclusions. A scientific conclusion is the culmination of scientific reasoning, not something completely divorced from the methodology that led to it.

The Eleventh Circuit applied the wrong standard of review in this case, and its analysis of the Plaintiffs' expert testimony under *Daubert* ignored the absence of reasoned explanations for the experts' conclusions. The decision below should be reversed and the District Court's judgment for the Defendants reinstated.

## ARGUMENT

### I. THE ELEVENTH CIRCUIT'S ONE-WAY STRICT SCRUTINY STANDARD OF REVIEW IS AT ODDS WITH BOTH *DAUBERT* AND THE PRINCIPLES OF APPELLATE REVIEW.

The one-way strict scrutiny standard adopted by the Eleventh Circuit is explicitly biased against district court decisions to exclude expert testimony, and thus directly at odds with this Court's mandate in *Daubert* that trial judges must assess the reliability and relevance of such evidence as a preliminary matter. The only precedent for discouraging the application of *Daubert* is the Third Circuit's decision in *Paoli*, which except for this case has not been followed by other courts. Even the Third Circuit has not always applied its own holding.

Beyond conflicting with *Daubert*, the one-way strict scrutiny approach reflects fundamental misunderstandings about appellate review of admissibility decisions. Appellate courts traditionally have accorded trial judges broad discretion in this area, especially for expert testimony, which requires detailed case-by-case analysis. The Federal Rules of Evidence have not changed this approach. Under Rule 104(a), trial judges have authority to determine

admissibility as a preliminary matter, and there is nothing in Rule 702 or elsewhere in the rules that would limit this authority based on the result-oriented preference for admissibility that the Third and Eleventh Circuits would impose. The "liberal thrust" of the rules removes arcane procedural impediments to the introduction of expert testimony, such as the former requirements regarding hypothetical questions, but the rules have not lowered the threshold of reliability and trustworthiness.

Varying the scope and intensity of appellate review based on the outcome below rather than the degree of authority and responsibility assigned to the trial judge upsets the allocation of roles between appellate and trial courts. Distinctly different roles have developed because the institutional strengths and advantages of trial courts are not the same as the strengths and advantages of appellate courts. Even if a statute or policy favors a party or an outcome, which is not the case in tort litigation, such a preference would not affect the rules of evidence. Nor would it affect the role of a trial court in determining if evidence is admissible.

#### A. One-Way Strict Scrutiny Is Contrary to *Daubert*.

When a witness testifies as an expert about science, his or her testimony must in fact constitute valid scientific knowledge that is relevant to the case at hand. This requirement flows naturally and directly from the plain language of Federal Rule of Evidence 702, which allows opinion testimony from a qualified expert if "scientific . . . knowledge will assist the trier of fact." As *Daubert* makes clear, "[t]he adjective 'scientific' implies a grounding in the methods and procedures of science. Similarly, the word 'knowledge' denotes more than subjective belief or unsupported speculation."<sup>1</sup> Requiring "that an expert's

<sup>1</sup> *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993).

testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability."<sup>2</sup>

*Daubert* further requires, in accordance with Rule 104(a) of the Federal Rules of Evidence, that trial judges must determine "at the outset" whether "the reasoning or methodology underlying [an expert's] testimony is scientifically valid and . . . whether that reasoning or methodology properly can be applied to the facts in issue."<sup>3</sup> Thus, trial courts are clearly obligated to exclude expert testimony when the expert's reasoning or methodology is invalid. Such exclusion may "on occasion [prevent] the jury from learning of authentic insights and innovations. [But that] . . . is the balance that is struck by Rules of Evidence designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes."<sup>4</sup>

In the almost four years since this Court's decision in *Daubert*, most District Courts have heeded its message.<sup>5</sup>

<sup>2</sup> *Id.*

<sup>3</sup> *Id.* at 592-93.

<sup>4</sup> *Id.* at 597.

<sup>5</sup> See, e.g., *Cuevas v. E.I. duPont de Nemours & Co.*, 956 F.Supp. 1306, 1312 (S.D. Miss. 1997) (excluding testimony of toxicologist and noting that toxicology "requires a determination of what dose-response relationship exists between the element in question and the harm that has possibly been caused"); *Cartwright v. Home Depot U.S.A., Inc.*, 936 F.Supp. 900, 903-4 (M.D. Fla. 1996) (excluding testimony of toxicologist regarding alleged link between latex paint and asthma where expert knew neither the plaintiffs' exposure level, nor the level required to cause asthma); *Haggerty v. Upjohn Co.*, 950 F.Supp. 1160, 1163 (S.D. Fla. 1996) (excluding medical causation testimony where expert's methodology consisted of reviewing various sources of information, such as case reports and references in textbooks); *In re TMI Litig. Consolidated Proceedings*, 927 F.Supp. 834, 858-66 (M.D. Pa. 1996) (summary judgment granted after extensive *Daubert* hearings resulted in exclusion of most of plaintiffs' expert testimony); *Cavallo v. Star Enterprise*, 892 F.Supp. 756, 763 (E.D. Va. 1995) (excluding testimony

Furthermore, most Circuit Courts have deferred to trial judges who have conducted the kind of inquiry into scientific validity that *Daubert* requires. Most appellate courts have applied an "abuse of discretion,"<sup>6</sup> "clear error,"<sup>7</sup> or "manifestly erroneous"<sup>8</sup> standard of review. Only the Third and Eleventh Circuits have bucked this trend by discouraging exclusion, and even the Third Circuit has not uniformly followed *Paoli*.<sup>9</sup> If the Eleventh Circuit's decision in this case is allowed to stand, however, much of the progress wrought by *Daubert* will be placed in serious jeopardy.

of toxicologist who had not used proper methodology), *aff'd in relevant part*, 100 F.3d 1150 (4th Cir. 1996), Petition for Cert. filed March 19, 1997, No. 96-1493; *Whiting v. Boston Edison Co.*, 891 F.Supp. 12, 18 (D. Mass. 1995) (excluding epidemiological testimony because expert's methodology was "replete with factual and mathematical errors"); *Schmaltz v. Norfolk & Western Railway Co.*, 878 F.Supp. 1119, 1121-22 (N.D. Ill. 1995) (excluding testimony regarding alleged link between pesticide exposure and reactive airway dysfunction syndrome where theory of causation had not been subject to peer review); *Wade-Greoux v. Whitehall Laboratories, Inc.*, 874 F.Supp. 1441, 1477 (D. V.I. 1994) (excluding testimony regarding alleged causal link between over-the-counter cold remedy and birth defects because experts' efforts to extrapolate directly from animal studies was not a valid scientific methodology), *aff'd*, 46 F.3d 1120 (3d Cir. 1994).

<sup>6</sup> See, e.g., *Cavallo v. Star Enterprise*, 100 F.3d 1150, 1154 (4th Cir. 1996) Petition for Cert. filed March 19, 1997, No. 96-1493; *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 320 (7th Cir. 1996); *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995).

<sup>7</sup> See, e.g., *Borawick v. Shay*, 68 F.3d 597, 601 (2d Cir. 1995).

<sup>8</sup> See, e.g., *United States v. Sepulveda*, 15 F.3d 1161, 1183 (1st Cir. 1993); *Allen v. Pennsylvania Engineering Corp.*, 102 F.3d 194, 196 (5th Cir. 1996).

<sup>9</sup> In *Habecker v. Clark Equipment Co.*, 36 F.3d 278, 289 (8th Cir. 1994), decided less than three weeks after *Paoli*, another panel of the circuit applied "a clear abuse of discretion" standard to affirm the trial court's exclusion of the plaintiff's expert testimony.

**B. One-Way Strict Scrutiny Is Contrary to the Traditional Deference Accorded Trial Court Evidentiary Rulings.**

The requirement that trial judges assess the scientific validity of an expert's reasoning and methodology reflects this Court's confidence in their capability to conduct such a review.<sup>10</sup> It also reflects the well-established pre-*Daubert* rule that a trial court's decision to admit or exclude expert evidence should be accorded great deference.<sup>11</sup> As this Court held in *Salem v. United States Lines Co.*,<sup>12</sup> such a decision is to be sustained unless it is "manifestly erroneous."<sup>13</sup> The *Salem* opinion cited with approval to *Congress and Empire Spring Co. v. Edgar*,<sup>14</sup> which held that

Cases arise where it is very much a matter of discretion with the court whether to receive or exclude the evidence; but the appellate court will not reverse in such a case, unless the ruling is manifestly erroneous.<sup>15</sup>

Pre-*Daubert* courts took this deferential approach for sound policy reasons that *Daubert* clearly reinforces. As

<sup>10</sup> *Daubert*, 509 U.S. at 593. See also *Michelson v. United States*, 335 U.S. 469, 488 (1948) (Frankfurter, J., concurring) ("If the United States District Courts are not manned by judges of such qualities, appellate review, no matter how stringent, can do very little to make up for the lack of them.")

<sup>11</sup> See, e.g., *Brown v. Parker-Hannifin Corp.*, 919 F.2d 308, 311 (5th Cir. 1990) (decision to exclude expert testimony reversed only for manifest error); *Logan v. Dayton, Hudson Corp.*, 865 F.2d 789, 790 (6th Cir. 1988) (abuse of discretion standard, which was "defined as a definite and firm conviction that the trial court committed a clear error of judgment"); *Universal Athletic Sales Co. v. American Gym, Recreational & Athletic Equip. Corp., Inc.*, 546 F.2d 530, 537 (3d Cir. 1976) (trial court decisions regarding competency of expert witnesses reviewed for abuse of discretion).

<sup>12</sup> 370 U.S. 31 (1962).

<sup>13</sup> *Id.* at 35.

<sup>14</sup> 99 U.S. (9 Otto) 645 (1879).

<sup>15</sup> *Id.* at 658.

Judge Weinstein and Professor Berger state in their treatise, decisions about the admissibility of expert testimony require detailed, case-by-case analysis, and trial judges therefore must be accorded broad discretion in deciding to admit or exclude such testimony.<sup>16</sup> *Daubert*, which specifically mandates more detailed trial court review of disputed expert evidence than in the past, can hardly be understood as having reduced the discretion accorded trial judges.<sup>17</sup>

**C. There Is No Justification for One-Way Strict Scrutiny in the Federal Rules of Evidence.**

An important part of the Eleventh Circuit's rationale for its one-way strict scrutiny standard of review was its understanding that "the Federal Rules of Evidence governing expert testimony display a preference for admissibility."<sup>18</sup> In fact, the rules do not incorporate such a preference. Though they were intended to "[relax] the traditional barriers to 'opinion' testimony,"<sup>19</sup> removing arcane and anti-

<sup>16</sup> 3 J. Weinstein & M. Berger, *WEINSTEIN'S EVIDENCE* ¶ 702(2) at 22-23 (1993).

<sup>17</sup> Even the Third and Eleventh Circuits routinely applied an abuse of discretion standard to the exclusion of unscientific opinion testimony well after the adoption of Rule 702. *United States v. Grizzle*, 933 F.2d 943, 949 (11th Cir. 1991); *United States v. Cross*, 928 F.2d 1030, 1049 (11th Cir. 1991) ("A trial court has wide discretion in determining whether to exclude expert testimony, and its action will be sustained on appeal unless manifestly erroneous."); *Gentry v. RTC*, 937 F.2d 899, 916 (3d Cir. 1991); *United States v. Stevens*, 935 F.2d 1380, 1397 (3d Cir. 1991) (Becker, J.). It was not until this Court's decision in *Daubert* that these two circuits discovered a preference for admission in Rule 702, and that this preference requires a special one-way strict scrutiny standard of review. It would appear that what is afoot is more a response to *Daubert* than to the Federal Rules of Evidence.

<sup>18</sup> *Joiner v. General Electric Co.*, 78 F.3d 524, 529 (11th Cir. 1996).

<sup>19</sup> *Daubert*, 509 U.S. at 588 (quoting *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 169 (1988)).

quoted impediments to the use of expert witnesses is not the same thing as creating a bias in favor of admitting their testimony. The rules do not relax the requirements of reliability and relevance.

The Advisory Committee Notes to Rule 702 make clear that this rule was intended to allow experts to explain and clarify evidence even if their testimony was not in the form of an opinion.

Since much of the criticism of expert testimony has centered upon the hypothetical question, it seems wise to recognize that opinions are not indispensable and to encourage the use of expert testimony in non-opinion form when counsel believes the trier can itself draw the requisite inference.

The rule was also intended to broaden the definition of expert to include anyone with specialized knowledge, whether obtained through education, training, or experience. The notes are absolutely silent, however, regarding any preference for admissibility or any willingness to accept less than reliable evidence.

This Court's decision in the *Beech Aircraft* case further discussed the rules' relaxation of traditional barriers. Again, there is no hint of any preference for admissibility. Instead, the decision observes that "Rules 702-705 permit experts to testify in the form of an opinion, and without any exclusion of opinions on 'ultimate issues.'" <sup>20</sup> Thus, the liberalization effected by the adoption of the Rules provides no justification for a one-way strict scrutiny standard of appellate review that discourages trial judges from evaluating expert testimony critically.

<sup>20</sup> *Beech Aircraft*, 488 U.S. at 169.

#### **D. One-Way Strict Scrutiny Upsets the Rational Allocation of Responsibility Between Trial and Appellate Courts.**

The outcome-dependent one-way strict scrutiny approach taken by the Eleventh Circuit in this case, and by the Third Circuit in *Paoli*, confounds the process of judicial review and disrupts the rational allocation of responsibility between trial and appellate courts. Just two years ago this very issue was addressed in *First Options of Chicago, Inc. v. Kaplan*.<sup>21</sup> The plaintiffs in *Kaplan* had filed suit in Federal District Court, hoping to vacate an arbitration award. When the court confirmed the award they appealed to the Third Circuit, which set it aside.<sup>22</sup> The appellate court exercised plenary review over the trial court's legal determinations, but to the extent factual findings were in dispute, the "scope of review [was] limited to whether those findings [were] clearly erroneous."<sup>23</sup>

On *certiorari* to this Court, the defendant in *Kaplan* took the position that the federal policy favoring arbitration should have controlled the standard under which both legal and factual findings were reviewed. According to the defendant's argument, an especially lenient "abuse of discretion" standard should have applied even as to questions of law "when reviewing district court decisions that confirm (but not those that set aside) arbitration awards."<sup>24</sup> The only support cited for this proposition was an Eleventh Circuit decision, which this Court rejected.

[T]he reviewing attitude that a court of appeals takes toward a district court decision should depend upon 'the respective institutional advantages of trial and

<sup>21</sup> 115 S. Ct. 1920 (1995).

<sup>22</sup> *Kaplan v. First Options of Chicago, Inc.*, 19 F.3d 1503 (3d Cir. 1994).

<sup>23</sup> *Id.* at 1509.

<sup>24</sup> *Kaplan*, 115 S. Ct. at 1926.

appellate courts,' not upon what standard of review will more likely produce a particular substantive result.<sup>25</sup>

The Eleventh Circuit's outcome-based one-way strict scrutiny standard in this case is just a reprise of the approach rejected in *Kaplan*. And it is just wrong. An appellate court reviewing evidentiary rulings on expert testimony should focus on whether the trial judge conducted an adequate inquiry into the reliability and relevance of the testimony, and should defer to the trial court's factual findings. Trial courts are in a much better position than appellate courts to determine such facts, as demonstrated all too well by the Eleventh Circuit's analysis of the expert evidence in this case.

## II. THE ELEVENTH CIRCUIT'S ANALYTICAL APPROACH IS A MISAPPLICATION OF *DAUBERT*.

The Eleventh Circuit compounded its erroneous standard of review by seriously misinterpreting and misapplying *Daubert's* core holding that expert scientific testimony must derive from valid scientific reasoning. Because of its one-way strict scrutiny standard, the court was too quick to review the expert testimony, and when it "looked hard" it looked in the wrong place. The District Court found there was no reasoned explanation connecting the studies relied upon by the plaintiffs' two principal experts to the conclusions they reached, but the Appellate Court essentially ignored the lack of connective reasoning and focused almost exclusively on the experts' qualifications and their bald assertions that they had used recognized and accepted procedures and methodologies. Rule 702, as interpreted in *Daubert*, plainly requires more.

<sup>25</sup> *Id.* (rejecting position taken in *Robbins v. Day*, 954 F.2d 679 (11th Cir. 1992), and quoting *Salve Regina College v. Russell*, 499 U.S. 225, 231-233 (1991)).

## A. *Daubert* Requires an Assessment of an Expert's Reasoning and Methodology.

Like the District Judge in this case, trial courts faced with disputed scientific evidence must undertake "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue."<sup>26</sup> This direct and unequivocal mandate derives from the *Daubert* Court's recognition that science is not a static body of knowledge, but "a process for proposing and refining theoretical explanations about the world that are subject to further testing and refinement."<sup>27</sup>

Thus, to determine if an expert's conclusions constitute admissible scientific knowledge under Rule 702, a court must focus on the reasoning process and methodology through which they were developed and validated, not just the conclusions themselves.<sup>28</sup> This emphasis on the "how and the why" behind a conclusion reflects *Daubert's* clear message that a scientist should not be allowed to venture opinions in court that would not pass muster as valid science outside the courtroom. When scientists evaluate scientific work they require justification in terms of reasoning and empirical support,<sup>29</sup> and under *Daubert* the law requires no less.

<sup>26</sup> *Daubert*, 509 U.S. at 592-93.

<sup>27</sup> *Id.* at 590 (quoting the brief *amicus curiae* of the American Association for the Advancement of Science and the National Academy of Sciences).

<sup>28</sup> *Id.* at 595.

<sup>29</sup> Frederick Suppe, *Afterword* to *THE STRUCTURE OF SCIENTIFIC THEORIES* 650 (F. Suppe, ed. 2d ed. 1977) ("[F]ar more of science is concerned with reasoning, argument, and marshaling evidence than with manipulating nature in the laboratory. . . . [A] central and characteristic activity of science is the use of reason in the [suggestion, development, and evaluation] of hypotheses and theories.") (emphasis in original).

**B. Unlike the District Court, the Eleventh Circuit Failed to Consider the Absence of a Reasoned Explanation for the Experts' Conclusions.**

Though the Eleventh Circuit ostensibly recognized that the admissibility of expert opinion testimony depends on the underlying reasoning or methodology,<sup>30</sup> its ruling was based almost exclusively on the experts' qualifications and their factual basis—exactly the kind of legalistic analysis of science that *Daubert* eschewed. The Appellate Court listed the information relied upon by the experts, but its only discussion of methodology or reasoning was the cursory observation that one expert had testified “that his methodology ‘has been the basis of diagnosis for hundreds of years,’” and that the other expert had “described his methodology as one ‘usually and generally followed by physicians and scientists’ ”<sup>31</sup>

These self-serving statements about the validity of the experts' methodology do not constitute an explanation of how they reached their conclusions. Indeed, by accepting such statements, the Eleventh Circuit allowed the experts to blur the important distinction between diagnosing *what disease* a patient has and *what caused the disease*.<sup>32</sup> In some cases diagnosis does identify cause; for example, a diagnosis that a child has the measles is also a determination that his or her symptoms were caused by the measles virus. For a chronic disease like lung cancer, however, diagnosis does not establish cause.<sup>33</sup> If it did, the expert testimony in this case would not be at issue.

<sup>30</sup> *Joiner*, 78 F.3d at 530.

<sup>31</sup> *Id.* at 532.

<sup>32</sup> The decisions doctors typically make relate to determining what disease a patient has and how to treat it, not necessarily to the cause of the disease. William B. Schwartz et al., *Decision Analysis and Clinical Judgment*, 55 AM. J. MED. 459 (1973).

<sup>33</sup> See, e.g. *Cavallo*, 892 F.Supp. at 771 (noting that a fundamental assumption underlying differential diagnosis is that “the

The Appellate Court's suggestion that “[o]pinions of any kind are derived from individual pieces of evidence, each of which by itself might not be conclusive, but when viewed in their entirety are the building blocks of a perfectly reasonable conclusion” is certainly correct,<sup>34</sup> but it begs the question of how the building blocks are put together, and why. Merely listing the ingredients for a cake does not explain how to bake it. As the dissent correctly pointed out, “an expert may not bombard the court with innumerable studies and then, with blue smoke and sleight of hand, leap to the conclusion. Instead, the expert must explain how the opinion drawn from each study is acceptable under *Daubert*.”<sup>35</sup>

**C. Reasoning and Methodology Are Inextricably Linked to Conclusions.**

The analytical gap between the studies relied upon by the experts in this case and the conclusions they reached went unaddressed largely because the Appellate Court misunderstood and misapplied this Court's admonition in *Daubert* to focus on principles and methodology rather than conclusions. Because conclusions represent the culmination of scientific reasoning and methodology, the only way to assess validity is to ask how a conclusion was reached, but that does not mean conclusions are completely divorced and separate from the underlying reasoning. Quite the contrary.

Even the *Paoli* decision recognized that if “a judge disagrees with the conclusions of an expert, it will generally be because he or she thinks that there is a mistake at some step in the investigative or reasoning process of the ex-

final, suspected ‘cause’ remaining after this process of elimination must actually be *capable* of causing the injury.”) (emphasis in original).

<sup>34</sup> *Joiner*, 78 F.3d at 532.

<sup>35</sup> *Id.* at 537.

pert.”<sup>36</sup> And as the Ninth Circuit observed in *Lust v. Merrel Dow Pharmaceuticals, Inc.*, “[w]hen a scientist claims to rely on a method practiced by most scientists, yet presents conclusions that are shared by no other scientist, the district court should be wary that the method has not been faithfully applied.”<sup>37</sup> In this case the issue should not have been at all difficult. The problem with the expert’s reasoning was more its absence than its deficiency. The District Court recognized this logical gap in their testimony and excluded it. The Eleventh Circuit should have affirmed.

#### CONCLUSION

For the foregoing reasons, CMA urges this Court to reject the Eleventh Circuit’s one-way strict scrutiny standard of review and to uphold the broad authority and discretion of trial courts to exclude putatively scientific evidence that does not accord with the reasoning and methodology of science. CMA accordingly prays this Court to reverse the Eleventh Circuit’s ruling in this case and to reinstate the District Court’s judgment in favor of the Petitioners.

Respectfully submitted,

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May 30, 1997

<sup>36</sup> *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 746 (3d Cir. 1994), cert. denied, 115 S.Ct. 1253 (1995).

<sup>37</sup> 89 F.3d 594, 598 (9th Cir. 1996).